Applicant: Philippe Rogueda Attorney's Docket No.: 06275-488US1 / 101141-1P US

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Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

- 1. (Currently amended) A process for producing micron-size crystalline particles of a drug substance which comprises mixing a solution of a drug substance to with a non-solvent in a container in the presence of ultrasonic energy.
- 2. (Currently amended) A process according to claim 1 in which the drug <u>substance</u> is a hydrophilic drug.
- 3. (Currently amended) A process according to claim 1-or 2 in which the solution comprises a small chain alcohol that is a solvent for a hydrophilic drugs substance is a small chain alcohol.
- 4. (Currently amended) A process according to any one of claims 1 to 3 claim 1 in which the solution comprises solvent for hydrophilic drugs is methanol.
- 5. (Currently amended) A process according to elaims 1 to 4 claim 1 in which the anti non-solvent for a hydrophilic drugs substance is acetionoitrile acetonitrile, 1,1,2,2 tetrafluoroethyl 2,2,2 trifluoroethylether, diethyl ether, acetone, ethyl acetate.
- 6. (Currently amended) A process according to claims 1 to 4 claim 1 in which the anti non-solvent for a hydrophilic drugs substance is diethyl ether or acetonitrile.
- 7. (Currently amended) A process according to claim 1 in which the drug <u>substance</u> is a hydrophobic drug.

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8. (Currently amended) A process according to elaims 1 or 7 claim 1 in which the solution comprises a solvent for hydrophobic drugs that is a small chain alocohol alcohol or choloroformchloroform.

- 9. (Currently amended) A process according to claim 8 in which the solution comprises a solvent for hydrophobic drugs-that is methanol or choloroformchloroform.
- 10. (Currently amended) A process according to claims 7 to 9-claim 1 in which the anti nonsolvent for a hydrophobic drugs substance is acetonitrile or water.
- (Currently amended) A process according to claims 7 to 9 claim 1 in which the anti non-11. solvent for a hydrophobic drugs substance is water.
- 12. (Currently amended) A process according to claim 1 in which the drug substance is selected from mometasone, ipratropium bromide, tiotropium and salts thereof, salmeterol, fluticasone propionate, beclomethasone dipropionate, reproterol, clenbuterol, rofleponide and salts, nedocromil, sodium cromoglycate, flunisolide, budesonide, formoterol fumarate dihydrate, Symbicort® (budesonide and formoterol fumarate dihydrate), terbutaline, terbutaline sulphate and base, salbutamol base and sulphate, fenoterol, 3-[2-(4-Hydroxy-2-oxo- 3H-1,3-benzothiazol-7yl) ethylamino]-N-[2-[2-(4-methylphenyl) ethoxylethyll propane sulphonamide, or hydrochloride.
- 13. (Currently amended) A process according to any one of claims 1 to 11 claim 1 in which the solution also conatins contains water.
- 14. (Currently amended) A process according to any one of claims 1 to 13-claim 1 in which the ultrasonic energy has a frequency of 20 kHz or more.
- 15. (Currently amended) A process according to any one of claims 1 to 14 claim 1 in which the ultrasonic energy has an amplitude of between $12 - 260 \mu m$.
- 16. (Currently amended) A process according to any one of claims 1 to 15-claim 1 in which the burst rate of the ultrasonic energy is from 10% to 100% per second.

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17. (Currently amended) A process according to any one of claims 1 to 16 claim 1 in which the reaction temperature is between 5 and 25°C.

- 18. (Currently amended) A drug substance prepared according to a process as defined in any one of claims 1 to 17 claim 1.
- 19. (Currently amended) A drug substance according to claim 18 which is mometasone, ipratropium bromide, tiotropium and salts thereof, salmeterol, fluticasone propionate, beclomethasone dipropionate, reproterol, clenbuterol, rofleponide and salts, nedocromil, sodium cromoglycate, flunisolide, budesonide, formoterol fumarate dihydrate, Symbicort® (budesonide and formoterol fumarate dihydrate), terbutaline, terbutaline sulphate and base, salbutamol base and sulphate, fenoterol, 3-[2-(4-Hydroxy-2-oxo-3H-1,3-benzothiazol-7yl) ethylamino]-N-[2-[2-(4-methylphenyl) ethoxy]ethyl] propane sulphonamide, or hydrochloride.
- 20. (Currently amended) A drug substance according to any one of claims 18 or 19 claim 18 having a particle size of 1 to 10 μm.